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SAN 2004-350

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3000930670

June 1, 2004

Frank Delcich, CEO
Pacific Seafood Group
16797 SE 130th Avenue
Clackamas, Oregon 97015

WARNING LETTER

Dear Mr. Delcich:

On April 15, 27, 30, and May 4, 2004, the U.S. Food and Drug Administration (FDA) inspected your seafood firm, Craig & Hamilton Meat Co., located at 721 North Union Street, Stockton, California and found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR § 123). These deviations cause your fish and fishery products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the seafood products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

Your serious HACCP deviations are as follows:

1. You must conduct or have conducted for you a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR § 123.6(a) and (b). However, your firm does not have a HACCP plan for cooked ready-to-eat whole crab, crabmeat, and sectioned cracked crab to control the food safety hazard of pathogens and for vacuum-packaged cooked imitation crab to control the food safety hazards of *Clostridium botulinum* toxin and pathogen growth. If any of the cooked ready-to-eat crab products are vacuum-packaged, you must control the food safety hazards of both *Clostridium botulinum* toxin and pathogen growth.

We note that you started to develop HACCP plans during FDA inspection. However, note that in accordance with 21 CFR § 123.6(b), a HACCP plan shall be specific to each kind of fish and fishery product processed by the processor.

The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped. Your plan groups all pre-packaged seafood (fresh, frozen, and dry storage product) together, contrary to the foregoing requirement.

2. You must maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by 21 CFR § 123.11(b), to comply with 21 CFR § 123.11(c). However, your firm does not maintain the following sanitation monitoring records, which are required for the processing of crab, crabmeat, and sectioned cracked crab to control the food safety hazard of pathogen growth; and of vacuum-packaged cooked imitation crab to control the food safety hazards of *Clostridium botulinum* toxin and pathogen growth.

- Safety of the water
- Condition and cleanliness of food-contact surfaces
- Prevention of cross-contamination
- Maintenance of hand washing, hand sanitizing, and toilet facilities
- Protection of food, food packaging material, and food contact surfaces from adulteration with contaminants
- Proper labeling, storage, and use of toxic compounds
- Control of employee health conditions that could result in microbiological contamination, and
- Exclusion of pests from the facility.

In accordance with 21 CFR § 123.3(k)(1), the term “processing” includes holding fish or fishery products.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR § 123.11(b). However, your firm did not monitor
 - a. Sanitation for the prevention of cross contamination with sufficient frequency to ensure control as evidenced by:
 - broken glass, broken pieces of Styrofoam, and various other debris piled up on the floor of a closet adjacent to the fish room;
 - an orange peel found in a stack of pallets in the storage room adjacent to the freezer;
 - debris on the floor and on shelving in a room located in the south end of the building;
 - standing water in the southwest corner of the fish room;
 - murky water in the drain in the holding room adjacent to the fish room;

- holes in the walls of the central holding room; and
 - sagging ceiling in the walkway between the fish room and the holding room.
- b. Exclusion of pests from the facility as evidenced by our observation of two dead insects and three flying insects in the facility.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with Dennis J. Barone, General Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act and the seafood HACCP regulations.

Failure to promptly correct these violations may result in regulatory action by FDA without further notice. For instance, we may move to seize your products and/or enjoin your firm from operating.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the deviations conveyed to you by FDA at the close of the inspection. Your response should outline the specific things you have done and are doing to correct the above-listed deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you have not completed all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Barbara J. Cassens
District Director
San Francisco District

Enclosure:
Form FDA 483